

**510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS****1. Classification and Device Name****Classification Name**

Magnetic Resonance Diagnostic Device

AUG 17 2012

**Model Number**

MJAH-167A

**Trade/Propriety Name**

Octave SPEEDER Head

**2. Establishment Registration**

2020563

**3. Contact Person, U.S. Agent Name and Address****Contact Person**

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**U.S. Agent/Official Correspondent**

Paul Biggins, Director, Regulatory Affairs

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**Address:**

Toshiba America Medical Systems, Inc. (TAMS)

2441 Michelle Drive

Tustin, CA 92780

**4. Manufacturing Site**

Toshiba Medical Systems Corporation (TMSC)

1385, Shimoishigami, Otawara-Shi, Tochigi 324-8550, Japan

**5. Date of Submission**

June 28, 2012 (revised 7/24/2012)

**6. Device Intended Use****Field Strength**

1.5 T

**Resonant Nucleus**

Hydrogen

**Anatomical Region of Interest**

Head, cervical region and upper chest.

**Diagnostic Use**

Diagnostic imaging of the the brain, cervical spine, and soft tissue and vasculature of the head, neck and upper chest.

**7. Device Description**

The Octave SPEEDER Head is a receive-only phased Array Coil that can receive NMR signal from head, cervical region and upper chest. The coil consists two parts of a head base, a removable anterior coil. The head base includes 7 coil elements, which are divided into 3 sections. The removable anterior coil includes 4 coil elements, which are divided into 2 sections. Users select the sections according to region of interest via a system user interface. The PC board switches transmit mode and receive mode with PIN diode. This coil is detuned during transmission by our QD whole body coil by means of activating the PIN diodes (transmit mode) and tuned during no transmission by means of not activating the PIN diodes (receive mode).

**8. Indication for Use**

The Octave SPEEDER Head is intended for imaging of the brain, cervical spine, and soft tissue and vasculature of the head, neck and upper chest.

The MJAH-167A is intended to be used on a Toshiba 1.5T MR System

**9. Design Change**

The SPEEDER technology has been previously cleared under K083014 as an Atlas SPEEDER Head/Cervical coil. The primary difference is the creation of an 8ch SPEEDER Head. The new Octave (8ch) SPEEDER Head will use the same SPEEDER technology as other cleared SPEEDER devices.

**10. Safety Parameter****Maximum static field strength**

1.5 T

**Maximum dB/dt**

1st operation mode specified in IEC60601-2-33 (2002)

**Maximum SAR**

1st operation mode specified in IEC60601-2-33 (2002)

**Peak and A-weighted Acoustic Noise Level**

Not applicable

**Biocompatibility**

All patient contacting materials have a history of use or test data that demonstrates its biocompatibility, i.e., non-toxic, non-irritating.

**11. Summary of Testing**

Testing was conducted utilizing phantoms and accepted imaging quality metrics.

**12. Imaging Performance Parameter**

Sample phantom images and clinical images are presented in Appendix F & G.

**13. Software**

The Octave SPEEDER Head coil does not contain software.

**14. Equivalency Information**

Toshiba Medical Systems Corporation believes that this Octave SPEEDER Head is substantially equivalent to the current Atlas SPEEDER Head/Cervical [K083014]. Testing was done in accordance with applicable recognized consensus standards as listed below.

IEC60601-1 (1998), Amd1 (1991), Amd2 (1995)  
IEC 60601-2 (2001), Amd1 (2004)  
IEC60601-1-6 (2006)  
IEC62366 (2007)  
IEC60601-2-33 (2002), Amd1 (2005), Amd2 (2007)

**15. Conclusion**

The new Octave SPEEDER Head (MJAH-167A) does not change the indication for use or the intended use of the predicate device. The safety and effectiveness has been verified via risk management and application of design controls to the new Octave SPEEDER Head.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Toshiba Medical System Corporation, Japan  
% Mr. Paul Biggins  
Director Regulatory Affairs/US Agent  
Toshiba America Medical Systems, Inc.  
2441 Michelle Drive  
TUSTIN CA 92780

AUG 17 2012

Re: K121910

Trade/Device Name: Octave SPEEDER Head; MJAH-167A  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: MOS  
Dated: July 24, 2012  
Received: July 26, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

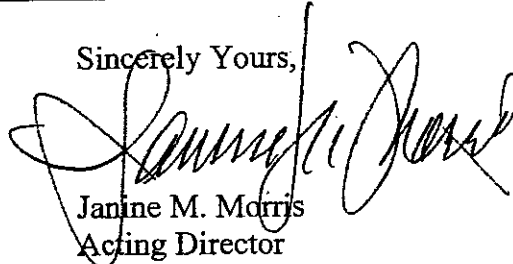
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

K121910

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**Indications for Use**

510(k) Number (if known): K121910

Device Name: Octave SPEEDER Head, MJAH-167A

Indications for Use:

The Octave SPEEDER Head is intended for imaging of the brain, cervical spine, and soft tissue and vasculature of the head, neck and upper chest.

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Radiological Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121910